

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY



(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

REC'D 20 JUN 2006

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Applicant's or agent's file reference 80442 WO	FOR FURTHER ACTION		See Form PCT/PEA/416
International application No. PCT/EP2005/000808	International filing date (day/month/year) 27.01.2005	Priority date (day/month/year) 28.01.2004	
International Patent Classification (IPC) or national classification and IPC INV. A23L1/30 A61K31/205			
Applicant NESTEC S.A. et al.			
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input checked="" type="checkbox"/> sent to the applicant and to the International Bureau) a total of 3 sheets, as follows:</p> <p><input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>			
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>			
Date of submission of the demand 23.08.2005		Date of completion of this report 19.06.2006	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized officer Uhl, M Telephone No. +49 89 2399-8654 	

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2005/000808

Box No. I Basis of the report

1. With regard to the **language**, this report is based on
- ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
 - ☐ international search (under Rules 12.3(a) and 23.1(b))
 - ☐ publication of the international application (under Rule 12.4(a))
 - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))
2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report):*

Description, Pages

1-17 as originally filed

Claims, Numbers

1-18 received on 20.03.2006 with letter of 17.03.2006

Drawings, Sheets

1/1 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages
 - ☐ the claims, Nos.
 - ☐ the drawings, sheets/figs
 - ☐ the sequence listing (*specify*):
 - ☐ any table(s) related to sequence listing (*specify*):

* If item 4 applies, some or all of these sheets may be marked "superseded."

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2005/000808

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 1-3, 5-17

because:

- ☒ the said international application, or the said claims Nos. 1-3, 5-17 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed (*specify*).
- ☐ no international search report has been established for the said claims Nos.
- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:
 - ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
 - ☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
 - ☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rules 13*ter*.1(a) or (b) and 13*ter*.2.
- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions, and such tables were not available to the International Preliminary Examining Authority in a form and manner acceptable to it.
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY**

International application No.
PCT/EP2005/000808

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	4,5, 18
	No: Claims	
Inventive step (IS)	Yes: Claims	4,5
	No: Claims	18
Industrial applicability (IA)	Yes: Claims	4,5,18
	No: Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Do: RU-C1-2 187 229

D2: US 2003/060503

D3: WO 02/11717

D4: US 2002/077349

D5: US-B1-6 503 506

1. Claims 1-3 and 6-17 are still -even after reformulation- formulated in a way that it includes non-medical as well as medical uses as ingestible composition includes non-medicaments as well (see claim 16). However, non-medical uses have to be claimed differently. To establish novelty, different features as the intended therapeutic indication have to be defined in view of the prior art. For the time being the non-therapeutic part of these claims is not novel over the prior art as for a non-therapeutic use the aim to increase the lipid secretion in the sebum is not relevant. Only in the strictly followed second-medical-use format directed to the use to manufacture a medicament -and not only a composition- for the treatment of a disease -and not only an unspecified increase of the lipid secretion in the sebum- the indication can establish novelty, like in the subject matter of claims 4 and 5. In view of the documents as cited in the international search report the subject matter of claims 1-3 and 6-17 are not novel over the prior art in view of this non-therapeutic part of subject matter included in the contested claims. DO discloses compositions with L-carnitine and -among others- vitamin C which is a known antioxidative agent. It is not necessary that this is discussed in Do. D2 and D3 disclose compositions with L-carnitine and coenzyme Q and alpha- lipoic acid. D4 discloses lipoic acid as antioxidant and a carnitine product, which also comprises L-carnitine. D5 discloses compositions comprising L-carnitine and antioxidants (fruit polyphenols). None of them discloses the aim to increase the lipid secretion in sebum. However this is not relevant for the evaluation of the non-therapeutic part of the contested claims as set out above.
2. The subject matter of claims 4 and 5 with a clear reference to dermatitis as medical indication is sufficiently clear second-medical-use and considered novel and inventive

in view of the prior art cited in the international search report (Art.33(1),(2) and (3) PCT).

3. The subject matter of claim 18 is new by the choice of special antioxidative agents. However all those antioxidative agents are well known equivalents of those already used together with L-carnitine in food or food supplements or pet food. Again their acting together in the human or animal skin is not relevant for evaluation. For the inventive step of the subject matter of a product claim the only question is whether it was evident to combine L-carnitine and antioxidants in e.g. food or food supplements. In case the special choice of antioxidants has an technical effect this should be shown by comparative experimentation with the closest prior art (Article 33(1) and (3)PCT).